

## **REMARKS**

Claims 42, 43, 45, 46, 47, 52 and 53 are under examination and all stand currently rejected..

Claims 42 – 43; and 45-47 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Mudde (WO 1997/007218) in view of Virtala et al. (1996. J. Allergy Clin. Immun., Vol. 97(3): 781 - 787).

Claims 52 and 53 are deemed allowable but for their dependence on claims 42 and 45.

The following remarks have addressed all the grounds for rejection and/or objection or have otherwise rendered them moot. Applicants respectfully request the Examiner reconsider all outstanding rejections, and that they be withdrawn.

### **Examiner Interview**

Applicants gratefully acknowledge the Examiner's time and attention in the Examiner Interview held on **April 02, 2010**. The above claims were discussed and the Examiner agreed that the claims as written are patentably distinct from the combination of Mudde and Virtala for reasons elaborated upon below. Applicants respectfully appealed to the Examiner to withdraw the finality of the final rejection on the grounds that Mudde was being cited for the first time against the instant invention and to pass the claims to issue. The Examiner nevertheless deemed the final rejection to be proper. Applicants appealed to the Examiner to withdraw the final rejection nevertheless in view of the fact that the instant invention is patentable over the combination, the Examiner indicated that she preferred a formal response instead.

The remarks presented herein are thus pursuant to the Examiner's request for a formal response. Accordingly, it is believed that the claims as presented are allowable and Applicants respectfully solicit the Examiner's notification of allowability.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 42 – 43; and 45-47 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Mudde (WO 1997/007218) in view of Vrtala et al. (1996. J. Allergy Clin. Immun., Vol. 97(3): 781 - 787).

The Examiner asserts that Mudde teaches complexes of human IgG and antigen/allergen or a combination of antigens/allergens and that Mudde concerns fusion proteins between anti-CD32 molecules and a combination of antigens/allergens.

To cure the deficiency in Mudde et al., the Examiner asserts that Vrtala et al. teach the construction of expression plasmids for Phl p1, Phl p2 and Phl p 5. (page 782 col. 1).

The Examiner concludes that it would have been prima facie obvious at the time of applicant's invention to apply Vrtala et al., recombinant Phl p1, Phl p2 and Phl p5 to Mudde's fusion protein.

Applicants respectfully disagree and traverse as follows:

The following paragraphs from Mudde abstract the sum and substance of Mudde's teaching:

The present invention concerns fusion proteins comprising a) one or more antigens AND b) one or more moieties, such as from antibody molecules, interacting with human Fcγ receptor II (Fcγ) (CD32), hereinafter briefly named **"the fusion proteins according to the invention"**. Paragraph 4, Page 4. (Emphasis added)

The fusion proteins according to the invention overcome the problems due to the low affinity of human IgG molecules to CD32. By combining an aCD32 antibody having a Kd < 10<sup>-6</sup> with antigen, both negative (B cells) and positive effects of natural IgG molecules are obtained, including selective stimulation of the immune system leading to Th1/Th0 memory induction in the absence of antibody production. The effect is harmless and directs the immune response to antigen-presenting cells which express CD32, whereby the cells which predominantly express CD32A mediate antigen presentation leading to induction and activation of Th1 cells as a result of the IL-12 produced by the CD32A-expressing antigen-presenting cells. Paragraph 5, Page 4 – Paragraph 1, Page 5.

(Emphasis added).

The parts of the fusion protein which interact with the Fcγ receptors II may e.g. be either 1) complete or incomplete (modified) human or humanized IgG antibody moieties, as long as interaction with these receptors is still possible, which implies that the whole or part of the Fc fragment should be present; or 2) human or humanized αCD32 antibody moieties, or parts thereof, e.g. Fab fragments, which still specifically recognize and bind to FcγRII (CD32) antigen such as expressed on B cells, mast cells, monocytes and dendritic cells, e.g. manipulated human or humanized αCD32 or IgG antibody moieties, or parts thereof, which recognize FcγRII (CD32) with higher affinity than the native αCD32 or IgG antibodies. Paragraphs 4 and 5, Page 5.

Thus Mudde teaches a fusion protein of one or more antigens **AND** a CD32 interacting component such as a human or humanized IgG antibody. (See Paragraph 4, page 4 for Mudde's explicit definition of its "fusion protein").

Mudde further teaches that its fusion protein must necessarily contain the CD32 interacting member in order to overcome **"the problems due to the low affinity of human IgG molecules to CD32."**

Assuming the combination of Mudde and Vrtala is proper, the alleged combination does not anticipate or render obvious the claims of the present invention which are precisely and distinctly drawn to immunotherapeutic agents CONSISTING OF fusion proteins of timothy grass pollen allergens. Whereas the fusion protein of Mudde relates conjunctively to a fusion protein of allergen and antibody, said antibody deemed essential by Mudde to promote CD32 interaction, the fusion protein of the present invention consists only of timothy grass pollen allergens. For that at least, the claims of the instant invention are patentable over Mudde and Vrtala and Applicants thank the Examiner for agreeing to withdraw the rejection.

## **CONCLUSION**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants respectfully request that the Examiner reconsider

all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office action and, as such, the present application is in condition for allowance. Applicants wish to expedite the prosecution process and if the Examiner believes, for any reason that personal communication will help expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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